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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

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Executive Summary

Following is the Health Effects Division's (HED's) and Antimicrobials Division's (AD's) human health scoping document for the triazole-derived fungicide tebuconazole to support Registration Review. To evaluate the scope of work necessary to support Registration Review, previous risk assessments for tebuconazole have been considered; updates to its toxicity, exposure, and usage databases; and the latest Agency science policy and risk assessment methodologies. The most recent HED aggregate risk assessment for tebuconazole was completed in 2013 (D412600, B. O'Keefe, 12/31/2013). AD has not conducted a risk assessment for tebuconazole since the chemical was initially registered.

Tebuconazole is registered for use in/on numerous agricultural field and orchard crops, as a post-harvest use on several fruits, on commercial ornamentals and golf course turf; and on residential ornamentals and flowers. Additionally, there are registered uses of tebuconazole as an antimicrobial pesticide, including the preservation of wood, and as a material preservative in adhesives, coatings, glues, plastics and metalworking fluids.

The toxicological database for tebuconazole is complete. The target organs in both rodents and non-rodents are the liver, adrenals, and hematopoietic system. In addition, ocular lesions are seen in dogs (including lenticular degeneration and increased cataract formation) following subchronic and chronic exposure. Some of the toxicological effects of tebuconazole are consistent with those of other triazole-derivative chemicals. In particular, developmental toxicity and hepatocellular tumors are effects common to a number of these class of pesticides. The data indicated that with *in-utero* exposure to tebuconazole resulted in developmental effects in fetuses (rat, mouse and rabbit) and pups (rats). The point of departure for dietary (acute and chronic) and non- dietary (incidental oral, dermal and inhalation exposures) is based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring seen in the rat developmental neurotoxicity study at the lowest observed adverse effect level (LOAEL). A no observed adverse effect level (NOAEL) was not seen in the study. The Food Quality Protection Act (FQPA) Safety Factor is retained in the form of a LOAEL to NOAEL factor since a LOAEL was used for overall risk assessment. A 3X as opposed to a 10X was deemed appropriate based on quantifiable data and lack of residual uncertainties for pre and/or post-natal toxicity. Tebuconazole is classified as a Group C Chemical; "Possible Human Carcinogen". A human cancer risk assessment is not required since the chronic reference dose (cRfD) will be considered protective of all effects including cancer.

For Tebuconazole Conventional Uses
The residue chemistry database for tebuconazole is adequate to support current data requirements. Adequate metabolism studies (crops, livestock, and rotational crops), storage

stability, magnitude of the residue, and processing data are available to support the registered uses. Adequate methods are available for enforcement of the currently established tolerances.

New dietary risk assessments are not anticipated during Registration Review, unless there are increases to the drinking water exposure estimates that need to be incorporated.

Residential and occupational handler and post-application exposure assessments are reflective of maximum application rates and current exposure policies and data, and did not identify risks of concern. Updated occupational and residential handler exposure assessments are not anticipated to be needed during Registration Review. Although existing occupational and residential post-application assessments are reflective of current exposure policies and data, turf transferrable residue (TTR) and dislodgeable foliar residue (DFR) studies are not available and are required for tebuconazole during Registration Review, because estimated post-application exposures using default TTR and DFR values are not minimal in comparison to the level of concern. Therefore, HED may need to reassess these exposures using the results of the required TTR and DFR studies during Registration Review.

HED will also examine the need for a volatilization assessment, as well as evaluate the potential for exposure from spray drift during Registration Review. However, for tebuconazole, several end-use products are labeled for use on residential turf. Thus, the risk assessment for residential turf may potentially be considered protective of any type of exposure that would be associated with spray drift. Residential bystander exposures resulting from off-site transport (i.e., volatilization) may occur as a result of occupational applications of tebuconazole. The need for a bystander risk assessment for tebuconazole will be considered during Registration Review.

For Tebuconazole Antimicrobial Uses

AD anticipates the need to conduct new occupational risk assessments for all the antimicrobial uses of tebuconazole during Registration Review to ensure that the assessment is consistent with current AD policies and standards. In addition, AD will need to reassess residential exposures to treated wood products based on new wipe data that are anticipated as needed based on potential risks identified in the past residential risk assessment. Additional occupational and residential risk assessments will be conducted during Registration Review.

Exposure studies and use data will be needed for assessing the risk from the antimicrobial uses of tebuconazole. AD anticipates the need to conduct new occupational exposure assessments for Registration Review to support wood and material preservative uses and to conduct new residential applicator assessments to support the wood stain use. Dermal (Guideline 875.1200) and inhalation (Guideline 875. 1400) surrogate applicator data will be needed to assess human health risks for occupational exposure for uses of tebuconazole as a wood preservative (sapstain and pressure treatment) and material preservatives (liquid pour). Occupational as well as residential surrogate data are also needed for the wood stain use (airless sprayer and paint brush/roller). Product use data (Guideline 875.1700) are needed to clarify uses (particularly the use in plastics), application rates (wood retentions), and application equipment.

AD anticipates the need to conduct a residential post-application risk assessment based on potential risk concerns from the previous risk assessment (D346795, B. O'Keefe, 11/26/2007;

updated in D397518, B. O'Keefe, 04/30/2012). A wipe study will be needed (Guideline 875.2300) to quantify residues from treated decks at the highest wood retention rate for tebuconazole. Product use data (Guideline 875.1700) will also be needed. The new residue data are needed to refine the previous residential post-application assessment, which was based on surrogate data.

Aggregate
Aggregate exposure to tebuconazole is currently not of concern to HED. However, the short-term aggregate risk estimates will need reevaluation during Registration Review based on the submitted wood, TTR, and DFR studies.

Introduction

Tebuconazole is a triazole fungicide active ingredient that acts by inhibiting C14-demethylase, an enzyme which plays a role in sterol production in fungi. The most recent human health risk assessment for tebuconazole was completed in 2013 for tolerances on imported oranges and orange commodities (D412600, B. O'Keefe, 12/31/2013).

For Tebuconazole Conventional Uses
Tebuconazole is currently registered for use in/on the following use sites: 1) field and orchard/tree crops: almonds, apple, asparagus (domestic use and import), bananas, barley (field and seed treatment), beans, *Brassica* leafy greens, bulb vegetables, cherries, corn (sweet corn, field corn, field corn grown for seed, and popcorn, plus seed treatment), cotton, cucurbits, fruiting vegetables, garden beets, grapes, grasses (grown for seed), hops, lychee, oats (seed treatment), okra, peaches, peanuts, pistachios, plantain, pome fruit, soybean, stone fruit, sunflower, tree nuts, triticale (seed treatment), turnips, watermelon, wheat (field and seed treatment), and wine grapes; 2) post-harvest uses on cherry, mango and plum; 3) commercial ornamentals and golf course turf; and 4) residential ornamentals and flowers. There are existing tolerances with no US registration on coffee, garlic, onions, and oranges.

Tebuconazole end use products are formulated as liquids, flowable concentrates, granulars and ready-to-use solutions. Tebuconazole is also formulated into products with other fungicides. Applications can be made with ground, aerial, airblast, chemigation, hand held, or seed treatment equipment, as well as postharvest sprays.

Permanent tolerances are established for residues of tebuconazole in/on various plant commodities at levels ranging from 0.05 ppm in/on asparagus, bananas, field and popcorn grain, pome fruits, tree nuts, and sunflower seed to 55.0 ppm in/on grass seed screenings [40 CFR §180.474(a)(1)]. Permanent tolerances are also established for the combined residues of tebuconazole and its metabolite 1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol (HWG 2061) at 0.2 ppm in/on meat-byproducts of cattle, goats, horses, and sheep, and at 0.1 ppm in milk [40 CFR §180.474(a)(2)]. Tolerances with regional registrations are established in 40 CFR §180.474(c) on turnip roots at 0.5 ppm and turnip tops at 7.0 ppm.

Refer to Attachment 1 (Table 1) for the chemical identity of tebuconazole.

For Tebuconazole Antimicrobial Uses

Tebuconazole is registered for the preservation of wood intended for above-ground and/or in-ground contact, such as Ponderosa pine, Scots pine, Southern yellow pine, beech, oak, birch, and other wood species susceptible to decay by rotting fungi. Such uses include fence posts, poles, decks, millwork, posts, etc. Wood treatment applications may include sapstain and pressure treatment. Tebuconazole is commonly used in combination with copper and propiconazole for different copper azole formulations. In addition to its major use as a wood preservative, tebuconazole is also registered for use as a material preservative in adhesives, coatings, glues, plastics and metalworking fluids.

Hazard Identification/Toxicology

No new toxicity data have been submitted since the last risk assessment (D412600, B. O'Keefe. 12/31/2013). The toxicological database for tebuconazole is complete for risk assessment. Developmental toxicity studies are available in rats, rabbits, and mice; developmental toxicity studies in rats and mice were administered via the oral and dermal routes. A developmental neurotoxicity in rats is also available and currently provides the most sensitive toxicity endpoints and is used for establishing the points of departure (POD) for risk assessment for all exposure scenarios (Attachment 3).

With repeated dosing, the common effects were seen in the liver, adrenals, and hematopoietic system in both rodent and non-rodent species. In addition, ocular lesions are seen in dogs (including lenticular degeneration and increased cataract formation) following subchronic or chronic exposure.

Tebuconazole induced developmental effects in many oral developmental toxicity studies in rats, rabbits, and mice. In all three species the developmental effects mostly occurred at similar dose levels where maternal effects were found; however, the maternal effects were minimal and did not increase substantially in severity at higher dose levels. The prominent developmental effect was on the developing nervous system manifested as increased malformations of the nervous system and skull (including exencephaly and acrania, skull bone and vertebral anomalies). The developmental toxicity studies, including the developmental neurotoxicity study, demonstrate both quantitative and qualitative developmental susceptibility. Decreased absolute brain weight, morphometric measurements, and decreased motor activity were seen in the offsprings of rats in the developmental neurotoxicity study. In the reproductive toxicity study, adverse effects on offspring were manifested only as decreased pup body weight. However, prolonged gestation and dystocia, as well as decreased offspring survival (fewer pups born alive, more stillborn pups, and pup deaths during the first week after birth), were seen in the developmental neurotoxicity study.

In contrast, tebuconazole did not produce any developmental effects in dermal developmental toxicity studies in rats and mice at dose levels up to the limit dose (1000 mg/kg/day). Furthermore, the 28-day dermal toxicity study in rabbits found no effect at the limit dose (1000 mg/kg/day). However, none of these dermal development and dermal toxicity studies conducted measurements on brain morphometric measurements and absolute brain weight in the developing animals.

Tebuconazole induced an increase in the incidence of hepatocellular adenomas, carcinomas and combined adenomas/carcinomas in male and female mice, but it showed no mutagenic potential. Based on these findings, tebuconazole was classified as a Group C Chemical; "Possible Human Carcinogen". A human cancer risk assessment is not required since the chronic reference dose will be protective of all effects including cancer.

The target organs with tebuconazole are consistent with those of other triazole-derivative chemicals. In particular, developmental toxicity and hepatocellular tumors are effects common to a number of these pesticides in this class. Tebuconazole also shares common metabolites with other chemicals in this group, including free triazole (1,2,4-triazole) and triazole-conjugated plant metabolites (such as triazole alanine). These common metabolites were the subject of a recent aggregate risk assessment document (D426493, T. Morton, 04/09/13) updated to incorporate new uses of triazole-derivative fungicides.

The DNT was selected as the critical study for establishing the Point of Departure (POD) for overall risk assessment. The LOAEL of 8.8 mg/kg/day is based on decreased absolute brain weight, morphometric measurements, and decreased motor activity observed in the offsprings; a NOAEL was not established. Since a LOAEL was selected as the POD, the FQPA Safety Factor is retained in the form of a LOAEL to NOAEL uncertainty factor ((UF_L). Typically, the default 10X will be retained. However, in the case of tebuconazole, the FQPA Safety Factor is reduced to 3 based on quantifiable data as discussed below:

> A Bench Dose (BMD) analyses of the endpoints of concern in the DNT showed that all of the BMDLs (benchmark dose limit) to be 1-2x lower than the LOAEL. Therefore, an extrapolated NOAEL is not likely to be 10X lower than the LOAEL, therefore, a 3X uncertainty factor is adequate;
>
> The use of a 3X UF to the POD results in an extrapolated NOAEL of 2.9 mg/kg/day (8.8 mg/kg/day÷ 3= 2.9 mg/kg/day) which is comparable to the developmental NOAEL (3 mg/kg/day) established in the pre-natal developmental toxicity study in rats;
>
> The toxicology database is complete and there are no residual uncertainties for pre and/or post-natal toxicity.

Please refer to Attachment 3 for a summary of the toxicity endpoints, points of departure (PODs) and safety factors for tebuconazole, and to Attachment 4 for the complete toxicity profile tables for tebuconazole.

Conclusion: The toxicology database is adequate to support the existing registered uses and there are no additional data requirements at this time.

Residue Chemistry and Dietary Exposure

For Tebuconazole Conventional Uses

The nature of the residue in primary/rotational crops and livestock has been adequately defined. Tebuconazole (parent) is the residue of concern for risk assessment and for the tolerance expression for primary/rotational crops. For poultry and ruminant livestock, tebuconazole and free and conjugated HWG-2061 are the residues of concern for risk assessment and for the tolerance expression. For drinking water, the residue of concern is tebuconazole (parent only).

HED also has concern for residues of 1,2,4-triazole, triazolylalanine (TA), and triazolylacetic acid (TAA) in plants and livestock as a result of the use of tebuconazole. However, because separate endpoints for these compounds have been established, exposure and risk from free triazole and its conjugates will be addressed separately.

The existing residue chemistry database for tebuconazole is adequate to support current Registration Review data requirements. Adequate metabolism, enforcement methods, multiresidue methods, storage stability, field trials, processing and rotational crop data are available to support the registered uses.

Analytical reference standards for tebuconazole are currently available in the EPA National Pesticide Standards Repository with an expiration date of 4/26/2023 (personal communication with Theresa Cole, Analytical Chemistry Branch (ACB), 10/15/2015). An analytical reference standard for the *t*-butylhydroxy metabolite is currently available at the Repository with an expiration date of 3/24/2016.

Acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted in 2013 (D416473, M. Negussie, 12/18/2013). The acute and chronic dietary assessments were somewhat refined. For the acute assessment, anticipated residues for grapes, grape juice, and peaches were derived using the latest United States Department of Agriculture (USDA) Pesticide Data Program (PDP) monitoring data. Anticipated residues for all other registered and proposed food commodities were based on field trial data. Available processing data were used to refine anticipated residues for apples/pears (dried and juice), apricots (dried), cherry (juice), coffee (roasted bean), grapes (juice), orange (juice), plums (prunes/prune juice), peanut (oil), and tomatoes (paste and puree). For all other processed commodities, Dietary Exposure Evaluation Model (DEEM) (ver. 7.81) default processing factors were assumed.

A distribution of estimated concentrations of tebuconazole in drinking water was provided by the Environmental Fate and Effects Division (EFED) and incorporated directly into the acute dietary assessment (D412862, A. Shelby, 07/03/2013). The acute assessment was conducted using the full 30-year distribution of estimated residues in surface water generated by the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM-EXAMS) model. The highest exposure in surface water resulted from application of tebuconazole to Florida turf. For the chronic dietary exposure, the 1-in-10 year annual mean (chronic) concentration of 68.8 µg/L was used. Due to the chemical properties of tebuconazole, surface water estimated drinking water

concentrations (EDWCs) are much larger than ground water EDWCs, and therefore, PRZM-GW estimates do not impact the findings.

The acute dietary exposure to tebuconazole is below HED's level of concern for all population subgroups (<100% of the acute Population Adjusted Dose (aPAD)). Combined acute dietary exposure from food and drinking water at the 99.9th percentile of exposure utilized 45% of the aPAD for the general U.S. population and 84% of the aPAD for children 1 to 2 years old, the highest exposed population subgroup.

Chronic dietary exposure estimates for food and drinking water are well below HED's level of concern (<100% of the chronic Population Adjusted Dose (cPAD)) for all population subgroups. The chronic dietary exposure from food and drinking water utilized 6.7% of the cPAD for the general U.S. population and 14% of the cPAD for all infants (<1 year old), the highest exposed population subgroup.

For Tebuconazole Antimicrobial Registrations

EPA has not established tolerances or tolerance exemptions for residues for the antimicrobial uses of tebuconazole. Tebuconazole has not been cleared as a food additive by the US Food and Drug Administration (US FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 409. Although there are registered antimicrobial uses that could result in indirect food contact, these uses are expected to result in minimal dietary exposure compared to the conventional agricultural uses of tebuconazole (i.e., direct treatment to growing crops intended for human or animal consumption). Additionally, the conventional agricultural uses of tebuconazole do not result in dietary risks of concern. Therefore, a dietary exposure assessment is not anticipated for the antimicrobial uses of tebuconazole.

Conclusions: At the time of the Registration Review risk assessment, HED will review updates to the PDP monitoring data, the percent crop treated information, and changes in drinking water exposure estimates, and will conduct a revised dietary assessment if there are likely to be increases to the dietary exposure estimates.

Residential Exposure

For Tebuconazole Conventional Uses

There are existing uses of tebuconazole on golf course turf, flower gardens, trees, and ornamentals in residential settings that were previously assessed to reflect HED's 2012 Residential SOPs[1] along with policy changes for body weight assumptions. Residential exposure is expected to be short-term only; intermediate-term exposures are not likely because of the intermittent nature of applications in residential settings. Dermal and inhalation exposures for residential handlers were combined since the same endpoint and POD is used for both routes of exposure. All combined short-term risk estimates for residential handlers are not of concern to HED with margins of exposure (MOEs) ranging from 2,800 to 91,000. Adults and children golfing and adults working in gardens may receive post-application exposure to tebuconazole residues. Residential dermal post-application MOEs for all life stages range from 570 to 6,200.

[1] Available: http://www.epa.gov/pesticides/science/residential-exposure-sop.html

Turf Transferable Residue (TTR): In accordance with the updated Part 158 data requirements (2007), a TTR study is required for all occupational (e.g., sod farms, golf courses, parks, and recreational areas) or residential turf uses. As part of the recent revision to the *Health Effects Division's 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment*, HED analyzed all available data and selected new liquid and granular default values for the fraction of the application rate available for transfer after a turf application (F_{AR}).[2] These defaults are 1% for formulations applied as liquids (i.e., emulsifiable concentrates, liquids, wettable powders, dry flowables, etc.) and 0.2% for granular formulations. Of the available TTR studies submitted to the Agency, the maximum F_{AR} value seen using a liquid product was 6.1% or 6.1 times higher than the default residue transfer value. The maximum F_{AR} value seen in a TTR study using a granular product was 0.69% or 3.5X the default residue transfer value. Therefore, for both liquid and granular formulations, a calculated MOE of approximately 10 times higher than the level of concern (e.g., an MOE >1,000 if the LOC = 100) using the default residue transfer values would provide an adequate margin of safety for any potentially higher residues seen in a chemical-specific TTR study (*Guidance for Requiring/Waiving Turf Transferrable Residue (TTR) and Dislodgeable Foliar Residue (DFR) Studies*. 6/7/2012, Exposure Science Advisory Council). For tebuconazole, the LOC is 300, and therefore, an MOE >3,000 is needed to negate the requirement for a new TTR study. As a result, since the existing uses of tebuconazole result in post-application risk estimates < 3,000 using default values for the fraction of application rate available for transfer after a turf application, a TTR (875.2100) study is required for tebuconazole.

Spray Drift and Volatilization: Residential bystander exposures resulting from off-site transport (e.g., spray drift or volatilization) may occur as a result of applications of tebuconazole. The potential for spray drift will be quantitatively evaluated for each pesticide during the Registration Review process that ensures that all uses for that pesticide will be considered concurrently. The approach is outlined in the revised (2012) Standard Operating Procedures for Residential Risk Assessment (SOPs) – Residential Exposure Assessment Standard Operating Procedures, draft Addenda 1: Consideration of Spray Drift. This document outlines the quantification of indirect non-occupational exposure to drift. In terms of volatilization, the agency has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219). During Registration Review, the agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analyses are required for specific chemicals. However, for tebuconazole, several end-use products are labeled for use on residential turf. Thus, the risk assessment for that use may be considered protective of any type of exposure that would be associated with spray drift.

For Tebuconazole Antimicrobial Uses

AD anticipates the need to conduct a residential post-application risk assessment during Registration Review to reevaluate or evaluate existing uses of tebuconazole in treated stains and wood products, based on potential risk concerns from the last risk assessment (D346795, B. O'Keefe, 11/26/2007; updated in D397518, B. O'Keefe, 04/30/2012). A previous assessment was conducted for the residential use in order to assess aggregate exposure. AD anticipates the need to conduct residential handler dermal and inhalation risk assessments for the application of

[2] http://www.epa.gov/pesticides/science/residential-exposure-sop.html

treated stains. The residential exposure scenarios applicable to this use include applicator brush/roller and airless sprayer. Wood products commercially treated with end use products containing tebuconazole may be used for decks and children's play sets. Based on the previous risk assessment (D346795, B. O'Keefe, 11/26/2007; updated in D397518, B. O'Keefe, 04/30/2012), wipe studies (Guideline §875.2300) are needed to measure residues from treated decks at the highest wood retention rate for tebuconazole in order to refine the risk estimates.

Because tebuconazole is also registered for use in plastics, the Agency will also need product use information (Guideline §875.1700) to clarify whether tebuconazole is used to manufacture toys; if tebuconazole may be used in toys, a post-application incidental oral exposure assessment from use in/on plastics will be conducted during Registration Review.

Conclusions: Short-term residential exposures are expected from existing uses on golf course turf, ornamentals, treated plastics, and treated wood products and the exposure and risk assessments may need to be updated during Registration Review. The following studies will be needed to update the risk assessments: Guideline §875.2100 Turf transferable residues; Guideline §875.1700 Product Use Data on the use of tebuconazole in plastics and wood; and Guideline §875.2300 Wipe Study from the use of tebuconazole on treated wood.

The Agency will examine the need for a volatilization assessment, as well as evaluate the potential for exposure from spray drift during Registration Review. However, for tebuconazole, several end-use products are labeled for use on residential turf. Thus, the risk assessment for residential turf may be considered protective of any type of exposure that would be associated with spray drift. Residential bystander exposures resulting from off-site transport (i.e., volatilization) may occur as a result of occupational applications of tebuconazole. The need for a bystander risk assessment for tebuconazole will be considered during Registration Review.

Aggregate Risk Assessment

In accordance with the Food Quality Protection Act, HED must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. The acute and chronic aggregate risk assessments included food and drinking water. The short-term aggregate risk assessment included food, drinking water, and residential exposures. No intermediate-term aggregate risk assessment was conducted since all residential/recreational exposures are anticipated to be short-term in duration.

Acute and Chronic Aggregate: The 2013 acute and chronic aggregate risk assessments included exposure to tebuconazole residues in food and drinking water. Acute and chronic dietary risk estimates for food and drinking water exposure are below HED's level of concern (<100% of the aPAD and cPAD).

Short-term Aggregate: In 2013, a short-term aggregate risk assessment was completed for tebuconazole. For adults and children 6 to <11 years old, the short-term aggregate assessment combined the average food and drinking water exposures with post-application dermal exposures from garden ornamentals. For youths 11 to <16 years old, the short-term aggregate assessment combined the average food and drinking water exposures with post-application dermal exposures

from golf course turf. For small children (1 to <2 years old), the short-term aggregate assessment combined the average food and drinking water exposures with post-application incidental oral (hand-to-mouth) exposures from contact with pressure treated wood surfaces.

As noted in the Residential section above the residential exposure assessment will likely be needed once the new studies have been received. The short-term aggregate assessment will be re-evaluated when the residential assessment is updated.

Conclusions: Aggregate exposure to tebuconazole is currently not of concern to HED. However, the short-term aggregate risk estimates will likely need reevaluation during Registration Review based on the submitted wood, TTR, and DFR studies.

Occupational Exposure

Most occupational exposure scenarios for currently registered agricultural uses were previously assessed using updated exposure assessment policies and body weight assumptions. However, occupational exposure scenarios for some antimicrobial uses have not been previously assessed. For conventional uses, occupational handlers and post-application workers can become exposed to tebuconazole over short- or intermediate-term durations. Additionally, for some antimicrobial uses occupational handlers can become exposed to tebuconazole at short-, intermediate-, and long-term durations.

For Tebuconazole Conventional Uses

Occupational Handlers: Previous occupational handler exposure and risk assessments for tebuconazole were conducted at the maximum application rates and assumed the maximum area treated per day for all the registered use sites. Applications can be made with ground, aerial, airblast, chemigation, hand-held, or seed treatment equipment. Occupational exposure assessments have been updated in accordance with current HED policies and standard operating procedures. Risk estimates for all scenarios are not of concern, and therefore, unless new data comes in, HED does not anticipate the need to reassess these exposures during Registration Review. MOEs ranged from 300 to 17,000 for conventional field and tree crops, 400 to 19,000 for seed treatments, 2,300 to 18,000 for post-harvest fruit treatments and 700 to 8,700 for golf course turf.

Occupational Post-Application: Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for tebuconazole. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for tebuconazole.

Dermal post-application exposures for occupational workers have been previously assessed for all non-antimicrobial uses of tebuconazole. Risk estimates for the day of application for all crops are not of concern to HED with MOEs ranging from 300 to 12,000.

Turf Transferable Residue (TTR): As detailed above in the Residential Exposure section, in accordance with the updated Part 158 data requirements (2007), a TTR study is required for all occupational (e.g., sod farms, golf courses, parks, and recreational areas) or residential turf uses.

For tebuconazole, the LOC is 300, and therefore, an MOE >3,000 is needed to negate the requirement for a new TTR study. As a result, since the existing uses of tebuconazole result in post-application risk estimates < 3,000 using default values for the fraction of application rate available for transfer after a turf application, a TTR study is required for tebuconazole.

Note: In 1996, Bayer CropScience submitted a TTR study to EPA (MRID 44108303). The TTR data from this study were previously used as an estimate of day zero tebuconazole residues on treated turf (DP361303, B. O'Keefe, 12/28/09). However, based on a complete review of this study (D414822, B. O'Keefe, 10/31/2013) HED concluded that the study data should not be used as an estimate of day zero residues on turf.

Dislodegable Foliar Residue (DFR): In accordance with 40 CFR §158, DFR data are required for all occupational (e.g., crop, nursery, greenhouse use sites) or residential (e.g., ornamental and vegetable gardens, pick your own farms, retail tree farms) uses that could result in post-application exposure to foliage. In the absence of chemical-specific DFR data, EPA uses default values. The *2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment* includes an analysis of a number of DFR studies, which resulted in the selection of a revised default values for the fraction of the application rate available for transfer after a foliar application (F_{AR}). This value is based on an analysis of 19 DFR studies. Since that time, the Agricultural Re-entry Task Force has submitted information (MRID 49299201) that corrects an application rate error made in the original submission of "ARF039 – Determination of Dermal and Inhalation Exposure to Reentry Workers During Chrysanthemum Pinching in a Greenhouse" (EPA MRID 45344501). As a result of this submission, the default value of 25% was not changed as it still reflects a high-end, conservative value. However, it is important to note that the range of F_{AR} values was revised from 2% - 89% to 2% - 47%. In the data, a large range of transferability is observed and this variability can potentially be attributable to many factors such as active ingredient; formulation; field conditions in the studies; weather conditions (e.g., humidity); or many other difficult to quantify factors. Although witnessed across multiple chemicals, this range in F_{AR} values is not expected when considering DFR data for a single chemical. Because DFR data are not available for tebuconazole, EPA is using the default value of 25%. Although there may be a small degree of uncertainty in the use of the default DFR value for tebuconazole (i.e., there is a small chance that the F_{AR} value may exceed the applicable default value), it is likely that the health-protective aspects of EPA's occupational post-application assessment methodology will more than compensate for this potential uncertainty. For example, when assessing residential and occupational post-application exposure to gardens and ornamentals, EPA assumes the following: exposures occur to zero-day (i.e., day of application) residues every day of the assessed exposure duration (i.e., EPA assumes that no dissipation or degradation occurs, it doesn't rain, etc); individuals perform the same post-application activities performed in the transfer coefficient study day after day (e.g., weeding, harvesting, pruning, etc.); and individuals engage in these post-application activities for a high-end amount of time every day (represented by data reflecting time spent gardening based on survey data).

Given the conservatisms discussed above and the potential compounding nature of these conservatisms, EPA is able to rely upon the calculated exposure estimates with confidence that exposure is not being underestimated.

Since the estimated post-application exposure for occupational exposures for some crop use sites using default DFR values for tebuconazole is not minimal in comparison to the level of concern (i.e., the calculated MOE is not greater than 2 times higher than the level of concern, MOE = 600 compared to the LOC of 300); future refinements of this post-application exposure for tebuconazole may be necessary due to increased use of tebuconazole or advances in EPA risk assessments. Therefore, EPA is requiring the 40 CFR DFR data requirement to facilitate any necessary exposure assessments refinements and to further EPA's general understanding of the availability of dislodgeable foliar pesticide residues.

For Tebuconazole Antimicrobial Uses
Occupational exposure assessments for antimicrobial uses of tebuconazole have not been updated since the chemical was initially registered. As a result, AD will need to conduct new occupational risk assessments for all the specified antimicrobial uses in Registration Review in accordance with current policies.

Occupational Handlers: EPA will need to conduct an occupational exposure assessment for Registration Review to support wood and material preservation uses for tebuconazole. AD specific occupational exposure assessments will be needed to support current AD policies and standard operating procedures. Occupational workers are anticipated to become exposed to tebuconazole wood preservatives during wood treatment activities such as sapstain, pressure treatment, and remedial uses such as applying wood stains using a brush/roller and/or airless sprayer on decks. In addition, occupational workers could potentially become exposed through the dermal and inhalation routes from material preservatives from pouring liquids or from mists and vapors during metalworking operations (e.g., machinists). The agency anticipates the need to call in data (Guidelines §875.1200, §875.1400, and §875.1700) and use surrogate exposure to assess all of these handler exposures during Registration Review. The duration of exposure for the occupational uses for workers at wood treatment plants and for machinists at metal working fluids are considered to represent short (1 to 30 days), intermediate (30 days to 6 months), and long-term (> 6 months) durations of exposure as workers in these settings. All other exposures from uses such as staining and pouring activities are more episodic and will be of short- and intermediate-term durations.

Occupational Post-application: AD does not anticipate the need to conduct a post-application exposure assessment. Any exposure for wood pressure treatment plants and machinists will already be captured in the occupational handler assessment. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for tebuconazole.

Conclusions: The occupational handler and post-application exposure assessments for conventional uses are reflective of current exposure policies and data. There is sufficient information available to assess these occupational handler exposures, and therefore, updated occupational handler exposure assessments for these uses are not anticipated to be needed during Registration Review. However, some antimicrobial use sites will need to be assessed for occupational handler exposures. Post-application exposure assessments may need to be updated

during Registration Review, since new TTR and DFR studies are needed. These data may necessitate the need to update the post-application exposure assessments for some use sites.

Public Health and Pesticide Epidemiology Data

In the Main OPP Incident Data System (IDS), from January 1, 2010 to May 27, 2015, there were eight (8) incidents reported for the single chemical tebuconazole only in the database. These incidents were classified as moderate severity.

In the Aggregate IDS, from January 1, 2010 to May 27, 2015, there were 444 incidents reported involving tebuconazole. These incidents were classified as minor severity.

A query of the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR)-Pesticides database for 1998-2011 identifies 16 cases involving tebuconazole; two of which involve a single active ingredient. Both single active ingredient cases were low in severity. One case was an agricultural worker who was exposed while conducting routine fieldwork. The case reported a skin rash, cough, nausea, vomiting, stomach pain, and headache. The second case was a homeowner who applied the product in windy conditions and inhaled the product. This case reported dermal and ocular symptoms (skin pain and conjunctivitis).

The Agricultural Health Study (AHS) is a high quality, prospective epidemiology study evaluating the link between pesticide use and various health outcomes, including cancer. The AHS includes private and commercial pesticide applicators and their spouses. Tebuconazole is not included in the AHS, and therefore, this study does not provide information for this report.

Conclusion: Although there were a moderate number of tebuconazole incidents reported to Main and Aggregate IDS and SENSOR-Pesticides, most of these incidents were classified as low severity. The effects experienced were generally minimally traumatic and resolved rapidly and usually involved skin, eye or respiratory irritation. Based on the generally low severity of incidents reported to both IDS and SENSOR-Pesticides, there does not appear to be a concern at this time. The Agency will continue to monitor the incident data and if a concern is triggered, additional analysis will be conducted.

Tolerance Assessment and International Harmonization

Tolerances are established for plant commodities under 40 CFR §180.474(a)(1) for residues of tebuconazole. Compliance with the tolerance levels is to be determined by measuring only tebuconazole [α-[2-(4-chlorophenyl) ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol].

Tolerances are established for livestock commodities under 40 CFR §180.474(a)(2) for residues of tebuconazole. Compliance with the tolerance levels is to be determined by measuring the sum of tebuconazole [α-[2-(4-chlorophenyl) ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol] and its diol metabolite (1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol), calculated as the stoichiometric equivalent of tebuconazole.

Tolerances with regional registrations are established for residues of tebuconazole in/on turnip roots at 0.5 ppm and turnip tops at 7.0 ppm 40 CFR §180.474(c).

The tolerance expression under 40 CFR §180.474 is correct and reflects both the measurement and compliance statements addressing tebuconazole residues. Compliance with the tolerance levels is to be determined by measuring only tebuconazole in plants and the sum of tebuconazole and its diol metabolite in livestock commodities.

The US and Canadian tolerance expressions for plants and livestock are harmonized; whereas, the US and Codex tolerance expressions are harmonized for plants only. The Codex tolerance expression for livestock commodities includes parent only. Residue definition in the US includes parent and the metabolite. There are Codex and Canadian maximum residue limits (MRLs) established for residues of tebuconazole. The US and Codex MRLs are in harmony only on banana, cotton undelinted seed, plum (except prunes), tree nuts, and wheat grain. The US livestock tolerances are not harmonized with Codex except for byproducts of sheep and hogs. The US and Canadian tolerances are harmonized for several plant and livestock commodities. Please refer to Attachment 6.

Notes to CRM: The existing US tolerances for pistachio (0.05 ppm) need to be removed from 40 CFR §180.474(a) since this commodity is included in crop group tree nuts (0.05 ppm).

The established tolerances (listed below) need to be revised to include an additional significant figure (1.0 ppm rather than 1 ppm). This is in order to avoid the situation where rounding of a residue result to the level of precision of the tolerance expression would be considered non-violative (such as 1.4 ppm being rounded to 1 ppm).

Note to CRM: The existing regional registration for turnip tops (7.0 ppm) and roots (0.05 ppm) need to be removed from 40 CFR §180.474 (c) to 40 CFR §180.474 (a) (1) since the required additional data was submitted (D403309, 12/06/12).

Table 1. Tolerance Recommendations for Tebuconazole.

Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Pistachio	0.05	None	Remove Nut, tree, group 14 (0.05 ppm)
Peach	1.0	None	Remove Fruit, stone, group 12, except cherry (1.0 ppm)
Plum	1.0		
Tolerance Revisions for Correct Commodity Definition			
Brassica, leafy greens, subgroup 5B	2.5	2.5	Brassica, leafy greens, subgroup 5B, except turnip greens
Cherry, sweet, pre- and post-harvest	5.0	5.0	*Cherry*
Cherry, tart, pre- and post-harvest	5.0	5.0	
Grain aspirated fractions	16.0	16	*Grain, aspirated grain fractions*

Table 1. Tolerance Recommendations for Tebuconazole.			
Commodity	**Established Tolerance (ppm)**	**Recommended Tolerance (ppm)**	**Comments**
Mango, postharvest	0.15	0.15	*Mango*
Tolerance Revisions for Significant Figure (a)General (1)			
Apple, wet pomace	0.1	0.10	
Barley, grain	0.3	0.30	
Bean, dry seed	0.1	0.10	
Bean, succulent	0.1	0.10	
Coffee, roasted bean[1]	0.3	0.30	
Cotton, gin byproducts	25.0	25	
Grass, hay	25.0	25	
Grass, seed screenings	55.0	55	
Grass, straw	30.0	30	
Hop, dried cones	35.0	35	
Onion, bulb, subgroup 3-07A	0.2	0.20	
Peanut	0.1	0.10	
Sunflower, meal	0.2	0.20	
Sunflower, refined oil	0.2	0.20	
Vegetable, cucurbit, group 9	0.4	0.40	
Tolerance Revisions for Significant Figure (a)General (2)			
Cattle, meat byproducts	0.2	0.20	
Goat, meat byproducts	0.2	0.20	
Horse, meat byproducts	0.2	0.20	
Milk	0.1	0.10	
Sheep, meat byproducts	0.2	0.20	

Cumulative

Tebuconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at

http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.

Human Studies

The risk assessments which have been previously conducted for tebuconazole relied in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED), the Agricultural Handler Exposure Task Force (AHETF) database, the Outdoor Residential Exposure Task Force (ORETF), the Agricultural Reentry Task Force (ARTF) Database and the Antimicrobial Exposure Assessment Task Force II (AEATF II). EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.

Data Deficiencies

Occupational and residential exposure data are needed to support the registered uses of tebuconazole are listed in Table 2.

Table 2. Exposure Studies Needed for Tebuconazole.

Study Needed	Guideline	Applicator or Post-application Exposure Scenario
Foliar Dislodgeable Residue Dissipation Data	875.2100	Post-application worker or residential exposure
Turf Transferrable Residue Dissipation Data	875.2100	Post-application worker or residential exposure
Dermal Applicator Data	875.1200*	-Worker exposure to sapstain and pressure treatment -Open pour liquid preservatives -Applying wood stains using a brush/roller and/or airless sprayer on decks.
Inhalation Applicator Data	875.1400*	-Worker exposure to sapstain and pressure treatment -Open pour liquid preservatives -Applying wood stains using a brush/roller and/or airless sprayer on decks.
Product Use Data	875.1700	All Antimicrobial Uses Product use data is needed to clarify uses (particularly the use of plastics in toys), application rates and wood retentions, and application equipment.
Indoor Residue Data (wipe study)	875.2300	Dermal and Incidental Oral Exposures to Children playing on pressure treated decks and playground equipment (children aged 1 to 2).

* For products with both indoor and outdoor uses, and similar conditions of use, data are generally required for the indoor applications only.

References

Recent Memoranda Relevant to Registration Review of Tebuconazole			
Author	**DP/TXR #**	**Date**	**Title**
Human Health Risk Assessments			
B. O'Keefe	DP412600	12/31/13	Tebuconazole: Human Health Risk Assessment for Tolerance on Imported Oranges.
T. Morton	DP414592	10/24/13	Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address The New Section 3 Registrations For Use of Propiconazole on Rapeseed Crop Subgroup 20A; Use of Difenoconazole on Rapeseed Crop Subgroup 20A; and Use of Tebuconazole on Imported Oranges.
B. O'Keefe	DP402457	01/31/13	Tebuconazole: Human Health Risk Assessment for Tolerance Increases Based on Submission of Condition of Registration Requirements for Barley and Cantaloupe; and Crop Group Expansion for Fruiting Vegetable Crop Group 8-10.
B. O'Keefe	DP387596	11/30/11	Tebuconazole: Human Health Risk Assessment for Proposed Use on Almond, Apple, Cherry, Peanut, Pecan, Pistachio, Tree Nuts, Watermelon, and Wine Grapes.
B. O'Keefe	DP384949	02/14/11	Tebuconazole: Human Health Risk Assessment to Harmonize Tolerances of Tebuconazole in/on Oats and Wheat with Canada
B. O'Keefe	DP373948	02/19/10	Tebuconazole: Amended Human Health Risk Assessment to Clarify Anticipated Residue and Percent Crop Treated Information.
B. O'Keefe	DP3613058	12/28/09	Tebuconazole: Human Health Risk Assessment for Proposed Use on Ornamentals and Golf Course Turf.
B. O'Keefe	DP362718	12/28/09	Tebuconazole: Human Health Risk Assessment for Proposed Uses on Fruiting Vegetables (Crop Group 8).
S. Winfield	DP354807	07/22/08	Tebuconazole: Amendment to D258383 Human Health Risk assessment for Tebuconazole; Proposed Tolerances for Cherry, Plum, and Commodity Definition for Hops.
S. Winfield	DP353954	06/30/08	Tebuconazole: Amendment to D258383 Human Health Risk assessment for Tebuconazole; Proposed Tolerances for Tree Nut Group 14 and Pistachios
S. Winfield	DP252188	04/30/08	Tebuconazole: Amendment to D258383 Human Health Risk assessment for Tebuconazole; Proposed Tolerances for Tree Nut Group 14 and Pistachios
S. Winfield	DP252188	04/30/08	Tebuconazole: Addendum to Human Health Risk Assessment
S. Winfield	DP256074/ DP276447	04/18/08	Tebuconazole: Human Health Risk Assessment to support tolerances in/on Asparagus, Barley, Beans, Beets, Brassica leafy greens, Bulb Vegetables, Coffee (import), Commercial Ornamentals, Corn, Cotton, Cucurbits, Hops, Lychee, Mango, Okra, Pome fruit, Soybean, Stone fruit, Sunflower, Tree Nut Crop Group, Turf, Turnips and Wheat.
Residue Chemistry			
M. Negussie	DP416474	12/18/13	Tebuconazole. Request to Establish a Tolerance for Imported Oranges. Summary of Analytical Chemistry and Residue Data.
Dietary Exposure Assessment			
M. Negussie	DP416473	12/18/13	Tebuconazole: Acute and Chronic Aggregate Dietary Exposure and Risk Assessments for Establishment of a Tolerance for Imported Oranges.
Occupational and Residential Exposure Assessments			
B. O'Keefe	DP408080	10/31/13	Tebuconazole. Occupational and Residential Exposure Assessment for a New Use on Home Lawns, Athletic Fields, and Sod.

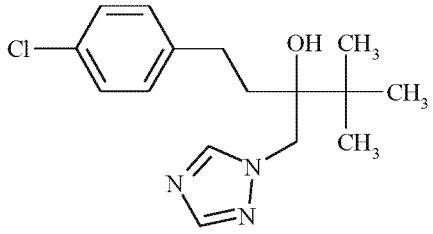
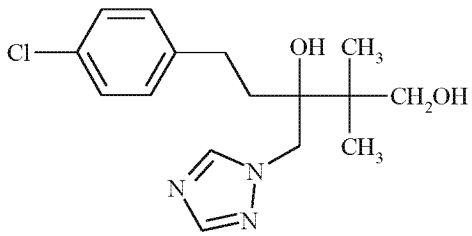
Recent Memoranda Relevant to Registration Review of Tebuconazole			
Author	**DP/TXR #**	**Date**	**Title**
B. O'Keefe	DP405729	06/06/13	Tebuconazole. Occupational and Residential Exposure Assessment for a New Granular Formulation for Use on Golf Course Turf and Residential Ornamentals.
B. O'Keefe	DP397518	04/30/12	Tebuconazole: Occupational Exposure and Risk Assessment for Proposed Increase in Application Rate for Golf Course Turf.
B. O'Keefe	DP389289	08/05/11	Tebuconazole: Occupational Exposure and Risk Assessment for Proposed Increase in Application Rate for Golf Course Turf.
B. O'Keefe	DP376329	04/09/10	Amendment: Tebuconazole: Occupational and Residential Exposure Assessment for Proposed Uses on Ornamentals and Golf Course Turf
B. O'Keefe	DP375909	03/29/10	Tebuconazole: Occupational and Residential Exposure Assessment for Proposed Uses on Barley, Pecan, Soybean, and Wheat on the Absolute 500 SC Fungicide Label
B. O'Keefe	DP361303	12/28/09	Tebuconazole: Occupational and Residential Exposure Assessment for Proposed Uses on Ornamentals and Golf Course Turf
B. O'Keefe	DP362766	12/28/09	Tebuconazole: Occupational and Residential Exposure Assessment for Proposed Uses on Fruiting Vegetables (crop group 8)
B. O'Keefe	DP315464	04/16/08	Tebuconazole: Occupational Exposure and Risk Assessment to Support Requests for Proposed Uses on Asparagus, Beans (Fresh & Dry), Bulb Vegetables, Corn, Cotton, Cucurbits, Garden Beet, Hops, Leafy *Brassica* Greens, Lychee, Okra, Pome Fruit, Soybean, Stone Fruit, Sunflower, Turnips, Golf Course Turf, Ornamentals, plus Post-Harvest Use on Cherry, Plum & Mango, & Seed Treatment of Corn Seed.
B. O'Keefe	DP349913	03/13/08	Tebuconazole: Occupational Exposure and Risk Assessment of Proposed Uses on Wheat, Barley, and Tree Nuts.
B. O'Keefe	DP349926	03/13/08	Tebuconazole: Residential Exposure and Risk Assessment of Proposed Use on Golf Course Turf and Existing Uses on Residential Ornamentals.
B. O'Keefe	DP346795	11/26/07	Tebuconazole: Residential Exposure and Risk Assessment of Existing Antimicrobial Uses on Wood Products and in Paints.
Incident Report			
S. Recore	D429846	10/28/15	Tebuconazole: Tier I Review of Human Incidents

Attachments

1. Chemical Identity Table
2. Physicochemical Properties of Technical Grade Tebuconazole Table
3. Endpoint Selection Table
4. Toxicity Profile Tables
5. Toxicology Data Requirements Table
6. Tolerance/MRL Table

Attachment 1

Chemical Identity Table

Table A.1. Nomenclature of Tebuconazole and its Regulated Metabolite.	
Compound	
Common name	Tebuconazole
Company experimental name	HWG 1608
IUPAC name	(*RS*)-1-*p*-chlorophenyl-4,4-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)pentan-3-ol
CAS name	α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol
CAS registry number	107534-96-3
Molecular weight	307.8
End-use products (EP)	FOLICUR® 25EW (25% w/v 250 g/L ; EPA Reg. No. 264-748)
Metabolite	
Common name	*t*-butylhydroxy-tebuconazole
Company experimental name	HWG 2061
IUPAC name	Not available
CAS name	1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-pentane-3,5-diol
CAS registry number	Not available
Molecular weight	323.8

Attachment 2

Table A.2. Physicochemical Properties of Tebuconazole.		
Parameter	Value	Reference
Melting point/range	104.7 °C	PP#9F3724/9F3818, 5/9/91, G. Otakie
pH	Not soluble enough	
Specific gravity (20 °C)	1.202 g/mL	
Water solubility (20 °C)	32 mg/L	
Solvent solubility (g/L at 20°C)	n-hexane 2-5 dichloromethane >200 2-propanol 100-200 toluene 50-100	
Vapor pressure	1.3 x 10^{-3} mPa (20 °C) 3.1 x 10^{-3} mPa (25 °C)	
Dissociation constant, pK_a	does not dissociate	
Octanol/water partition coefficient, Log(K_{OW})	3.7 at 20 °C	
UV/visible absorption spectrum	Not available	

Attachment 3

Summary of Toxicity Endpoints and Points of Departure of Tebuconazole

Table A.3. Summary of Toxicological Doses and Endpoints for Tebuconazole for Use in Dietary and Non-Occupational Human Health Risk Assessments.

Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	LOAEL = 8.8 mg/kg/day	UF_A= 10x UF_H=10x (UF_L)= 3x FQPA=1X	Acute RfD = 0.029 mg/kg/day aPAD = 0.029 mg/kg/day	Developmental Neurotoxicity Study - Rat. LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring.
Chronic Dietary (All Populations)	LOAEL = 8.8 mg/kg/day	UF_A= 10x UF_H=10x (UF_L)= 3x FQPA=1X	Chronic RfD = 0.029 mg/kg/day cPAD =0.029 mg/kg/day	Developmental Neurotoxicity Study - Rat. LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring.
Incidental Oral Short-Term (1-30 days) and Intermediate-term (30 days – 6 months)	LOAEL = 8.8 mg/kg/day	UF_A= 10x UF_H=10x (UF_L)= 3x FQPA=1X	Residential LOC for MOE = 300	Developmental Neurotoxicity Study - Rat. LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring.
Dermal (All durations)	LOAEL = 8.8 mg/kg/day	UF_A= 10x UF_H=10x UF_L= 3x DAF = 13%	Residential LOC for MOE = 300	Developmental Neurotoxicity Study - Rat. LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring.
Inhalation (All durations)	LOAEL = 8.8 mg/kg/day	UF_A= 10x UF_H=10x UF_L= 3x	Residential LOC for MOE = 300	Developmental Neurotoxicity Study - Rat. LOAEL = 8.8 mg/kg/day based on decreases in body weights, absolute brain weights, brain measurements and motor activity in offspring.
Cancer (oral, dermal, inhalation)	Classification: Group C- possible human with no quantification. The chronic risk assessment is considered to be protective of any cancer effects; therefore, a separate quantitative cancer risk assessment is not required.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable. DAF = dermal absorption factor.

Attachment 4

Toxicity Profile for Tebuconazole

Table A.4.1. Acute Toxicity Profile for Tebuconazole				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute oral [rat]	40700917	LD_{50} (fasted) = > 5000 mg/kg (M); 3933 mg/kg (F); (unfasted)=4264 mg/kg (M); 3352 mg/kg (F)	III
870.1200	Acute dermal [rat]	40700917 41290801	LD_{50} = >5000 mg/kg (M & F)	III
870.1300	Acute inhalation [rat]	40700922	LC_{50} (4 h, aerosol)= >371 mg/m^3 LC_{50} (4 h, dust)= >5093 mg/ m^3	II
870.2400	Acute eye irritation [rabbit]	40700925 40700917	Slight to Mild irritant	III
870.2500	Acute dermal irritation [rabbit]	40700917 40995910	Non-irritant	IV
870.2600	Skin sensitization [guinea pig]	40700928 41290802	No evidence of skin sensitization using the Buehler test	NA

Table A.4.2. Subchronic, Chronic and Other Toxicity Profile for Tebuconazole Technical.		
Guideline No. Study Type	**MRID No. (year) Doses/ Classification**	**Results**
870.3100 90-Day oral toxicity - rat	40700930 (1986) (0, 100, 400, 1600 ppm in diet); 0, 8.6, 34.8, 171.7 mg/kg/d (m); 0, 10.8, 46.5, 235.2 mg/kg/d (f) Acceptable/guideline	Male: NOAEL = 34.8 mg/kg/d; LOAEL= 171.7 mg/kg/d based on decreased body wt., body wt. gain, and histopathology findings. Female: NOAEL=10.8 mg/kg/d, LOAEL= 46.5 mg/kg/d based on histopathological changes in the adrenal gland.
870.3150 90-Day oral toxicity - dog	40700934 (1987) (0, 200, 1000, 5000 ppm in diet); 0, 73.7, 368.3, 1749.1 mg/kg/d (m); 0, 73.4, 351.8, 1724.8 mg/kg/d (f) Acceptable/guideline	NOAEL = 73.4/73.7 mg/kg/d (m/f) LOAEL = 368.3/ 351.8 mg/kg/d (m/f) based on decreased body wt. gain, food consumption and increased liver enzyme activities.
870.3200 21/28-Day dermal toxicity - rabbit	40700937 (1984) 0, 50, 250, 1000 mg/kg/day Acceptable/guideline	NOAEL = 1000 mg/kg/day. No dermal or systemic toxicity was seen.
870.3465 21-Day inhalation toxicity - rat	40700938 (1985) 0, 1.2, 10. 6, 155.8 mg/m^3 Acceptable/non-guideline	NOAEL = 10.6 mg/m^3/day (≈2.0 mg/kg/day) LOAEL = 155.8 mg/m^3/d (≈28 mg/kg/day) based on clinical signs (bristling coat).
870.3700a Prenatal developmental - rat	40700943 (1988) 0, 30, 60 , 120 mg/kg/d, GD 6-15 Acceptable/guideline	**Maternal** NOAEL = 30 mg/kg/day LOAEL=60 mg/kg/d based on increased liver wieght and liver/body weight ratios. **Developmental** NOAEL=30 mg/kg/day LOAEL =60 mg/kg/d based on delayed ossification of several bones and increased numbers of fetuses with supernumerary ribs.

Table A.4.2. Subchronic, Chronic and Other Toxicity Profile for Tebuconazole Technical.		
Guideline No. Study Type	**MRID No. (year) Doses/ Classification**	**Results**
870.3700a Prenatal developmental - rat (Dermal)	41450801 (1988) 0, 100, 300, 1000 mg/kg/d, GD 6-15 Acceptable/guideline	**Maternal** NOAEL= 1000 mg/kg/d **Developmental** NOAEL= 1000 mg/kg/d No evidence of maternal or developmental toxicity seen via dermal route.
870.3700a Prenatal developmental - mouse	40821501 (1988) 0, 10, 30, 100 mg/kg/d, GD 6-15 40821500 (1988) Supplementary study 0, 10, 20, 30, 100 mg/kg/d GD 6-15 Acceptable/guideline	**Maternal** NOAEL = 30 mg/kg/d LOAEL = 100 mg/kg/d based on increased hepatic triglycerides, pale lobular liver, increased severity of hepatic vacuoles and lipidosis. **Developmental** NOAEL = 10 mg/kg/d LOAEL = 30 mg/kg/d based on increased number of runts.
870.3700a Prenatal developmental - mouse	43776201, 43776202(1995) 0, 10, 30, 100 mg/kg/d, GD 6-15 Supplementary group 0, 1, 3 mg/kg/d GD 6-15 Acceptable/guideline	**Maternal:** NOAEL = 3 mg/kg/d LOAEL = 10 mg/kg/d based on increased hepatic enzyme induction and severity of vacuolization in liver cells. **Developmental**: NOAEL= 3 mg/kg/d LOAEL=10 mg/kg/d based on increased external, visceral, and skeletal malformation/variation in the head and skull.
870.3700a Prenatal developmental - mouse (Dermal)	42010301 (1990) 0,100,300,1000 mg/kg/d GD 6-15 Acceptable/guideline	**Maternal** NOAEL= 1000 mg/kg/d **Developmental** NOAEL= 1000 mg/kg/d No evidence of maternal or developmental toxicity seen via dermal route.
870.3700b Prenatal developmental - rabbit	40700945 (1987) 0, 10,30,100 mg/kg/d, GD 6-18 Acceptable/guideline	**Maternal** NOAEL = 30 mg/kg/d LOAEL = 100 mg/kg/d based on decreased body weight gain and food consumption. **Developmental** NOAEL = 30 mg/kg/d LOAEL = 100 mg/kg/d based on increased resorptions and post-implantation losses, decreased live fetuses/doe, and external and skeletal abnormalities.
870.3700b Prenatal developmental - rabbit	43776201 (1995) 0, 10, 30, 100 mg/kg/day GD 6-18 Acceptable/guideline	**Maternal** NOAEL = Not established (<10 mg/kg/d) LOAEL = 10 mg/kg/d based on increased incidence of single cell necrosis in liver cells. **Developmental** NOAEL = 10 mg/kg/d LOAEL = 30 mg/kg/d based on increased external and visceral malformation/variations.
870.3800 Reproduction and fertility effects - rat	40700946 (1987) 0, 100, 300, 1000 ppm in diet (equivalent to 0, 5, 15, 50 mg/kg/day) Acceptable/guideline	**Parental/Systemic** NOAEL = 15 mg/kg/day (m & f) LOAEL = 50 mg/kg/day based on increased severity of splenic hemosiderosis (m & f), increased incidence of splenic hematopoiesis (m), and decreased weight gain during gestation (f) **Reproductive** NOAEL = 50 mg/kg/day LOAEL = not determined **Offspring** NOAEL = 15 mg/kg/day LOAEL = 50 mg/kg/day based on decreased pup body wt.

Table A.4.2. Subchronic, Chronic and Other Toxicity Profile for Tebuconazole Technical.		
Guideline No. Study Type	**MRID No. (year) Doses/ Classification**	**Results**
870.4300 Chronic/ carcinogenicity - rat	40700939, 40816401 (1988) 0, 100, 300, 1000 ppm in diet; M: 0, 5.2, 15.9, 55 mg/kg/d; F: 0, 7.4, 22.8, 86.3 mg/kg/d Acceptable/guideline	Males: NOAEL = 15.9 mg/kg/d; LOAEL=55 mg/kg/day based on decreased testes weight. Females: NOAEL= 7.4 mg/kg/d; LOAEL=22.8 mg/kg/day based on decreased body wt. & wt. gain, decreased erythrocyte parameters and increased incidence of splenic hemosiderosis (increased erythrocyte clearance). No evidence of carcinogenicity at the doses tested.
870.4100b Chronic toxicity - dog	40700940 (1987) 0, 40, 200, 1000/2000 ppm in diet; 0, 15.5, 77.3, 483 mg/kg/d Acceptable/guideline	NOAEL = 15.5 mg/kg/day LOAEL = 77.3 mg/kg/day based on ocular lesions and changes in erythrocyte morphology (anisocytosis)
870.4100b Chronic toxicity - dog	42030601 (main) (1989) & 42537201 (suppl.) (1992); 0, 100, 150 ppm; M: 0, 2.96, 4.39 mg/kg/d F: 0, 2.94, 4.45 mg/kg/d Acceptable/guideline together with 40700940	NOAEL = 2.96 mg/kg/day (m), 2.94 mg/kg/d (f) LOAEL = 4.39 mg/kg/day (m), 4.45 mg/kg/d (f) based on lesions in the adrenal gland.
870.4200b Carcinogenicity - mouse	40700941 (1988) 0, 20, 60, 180 ppm in diet; M: 0, 5.9, 18.2, 53.1 mg/kg/d F: 0, 9.0, 26.1, 80.5 mg/kg/d 42175001 0, 500, 1500 ppm M: 0, 84.9, 279 mg/kg/day F: 0, 103.1, 365.5 mg/kg/day Acceptable/guideline	Male mice had statistically significant, dose-related increasing trends in hepatocellular adenomas, carcinomas and combined adenomas and/or carcinomas. There were also statistically significant differences in the pair-wise comparisons of the controls with the 1500 ppm dose group for hepatocellular adenomas (29% vs. 5% controls), hepatocellular carcinomas (21% vs. 0% controls) and combined adenomas and/or carcinomas (47% vs. 5% controls).
870.5100 Salmonella point mutation	40700947 & 40700948 (1988) Acceptable/guideline	Negative with or without activation at doses ranging from 39.5 to 450 µg/plate
870.5300 CHO-HGPRT forward mutation	40700949 (1988) Unacceptable/guideline	Negative with or without activation at concentrations ranging from 12.5-200 and 80-100 µg/mL, respectively; highest concentration tested did not produce high level of cytotoxicity.
870.5375 In vitro Cytogenetics (human lymphocytes)	40700953 (1988) Acceptable with activation; Unacceptable without activation	Negative for chromosome aberrations with activation (30-300 µg/mL) and without activation (10-300 µg/mL); highest dose not cytotoxic without activation.
870.5395 Mammalian erythrocyte micronucleus	40700951 (1985) Acceptable/guideline	Negative at all doses up to 2000 mg/kg bw
870.5450 Mouse dominant lethality	40700950 (1986) Unacceptable/guideline	Negative at 2000 mg/kg bw (only dose tested) during 12 serial mating periods; positive control was not included
870.5500 DNA damage and repair (*E.coli*)	40700955 (1983) Unacceptable/guideline	Negative with or without activation at concentrations ranging from 625-10,000 µg/plate); no growth inhibition zone detected

Table A.4.2. Subchronic, Chronic and Other Toxicity Profile for Tebuconazole Technical.		
Guideline No. Study Type	**MRID No. (year) Doses/ Classification**	**Results**
870.5550 Unscheduled DNA synthesis (rat hepatocytes)	40816402 (1988) Acceptable/guideline	No evidence of an increase in unscheduled DNA synthesis at 0.504-25.2 µg/mL
870.5900 Sister chromatid exchange (CHO cells *in vitro*)	40700952 (1987) Acceptable/guideline	Negative with and without activation with S9 at concentrations ranging from 4-30 µg/mL and 15-120 µg/mL, respectively.
870.6200a Acute neurotoxicity screening battery -rat	44449301, 44545701 (1997) 0, 21, 50, 103, 497, 950 mg/kg Unacceptable/Guideline (Upgradeable)	NOAEL = 50 mg/kg/day LOAEL = 100 mg/kg/day based on increased motor activity in males and females and decreased footsplay in females.
870.6200b Subchronic neurotoxicity screening battery -rat	44588001 (1998) 0, 100, 400, or 1600 ppm M: 0.00, 7.57, 29.2, 107 mg/kg/day F: 0.00, 8.81, 34.0, 122 mg/kg/day Unacceptable/Guideline (Not upgradeable)	NOAEL = 107 mg/kg/day LOAEL = Not determined [>107 mg/kg/day]
870.6300 Developmental neurotoxicity -rat	45074301 (2000) 0, 100, 300, 1000 ppm [GD/LD 0/0, 8.8/16.3, 22/41.3, 65/125.4 to dams], GD6 to LD11 Acceptable/Guideline	**Maternal** NOAEL = 22 mg/kg/day LOAEL = 65 mg/kg/day based on decreased body weight, body weight gain, and food consumption; prolonged gestation with mortality, increased number of dead fetuses. **Offspring** NOAEL = <8.8 mg/kg/day LOAEL = 8.8 mg/kg/day based on decreased body weight, decreased absolute brain weights and brain measurements, and decreased motor activity.
870.7485 Metabolism - rat	40995911, 40995912 (1987) Acceptable/guideline	98.1% of oral dose is absorbed. Over 87% of dose excreted in urine & feces within 72 hours after dosing. At sacrificed (72 hrs postdosing) total residue (minus GI tract) amounted to 0.63% of the dose. A total of 10 compounds were identified in excreta. A large fraction of the identified metabolites corresponded to successive oxidation steps of a methyl group of tebuconazole. At higher dose 920 mg/kg) changes in detoxification patterns may result from metabolic saturation.
870.7600 Dermal penetration - monkey	46634901 (2003) 132 µg/cm^2 tebuconazole in Folicur EW250, single 8 hr administration Acceptable/nonguideline	Estimated dermal absorption 23.1%. (including the fraction of the dose absorbed and the amount of dose remaining in the skin after washing).
Literature study: Developmental neurotoxicity /immunotoxicity	45486901 (2001), 45591701 (2002), 46146701 (2003) 0, 6, 20, 60 mg/kg (gavage) GD14-PND7 to dams, PND7-42 to offspring	Study evaluated reproductive, immuno-, and neurotoxicity in offspring. Identified one effect of concern: learning deficits in high dose offspring, evaluated starting on PND74. Neuropathological effects identified in the original study were retracted based on a pathology peer-review.

Table A.4.2. Subchronic, Chronic and Other Toxicity Profile for Tebuconazole Technical.		
Guideline No. Study Type	**MRID No. (year) Doses/ Classification**	**Results**
870.7800 Immunotoxicity	48769501 (2012) Acceptable/Guideline Doses: 0, 100, 300, 1000 ppm 0, 8.1, 24.3, 78.4 mg/kg/day	Systemic: NOAEL = 78.4 mg/kg/day LOAEL > 78.4 mg/kg/day Immunotoxicity: NOAEL = 78.4 mg/kg/day LOAEL = 78.4 mg/kg/day

Attachment 5

Toxicology Data Requirements

The requirements (40 CFR §158.340) for food and non-food uses for Tebuconazole are in Table 1. Use of the new guideline numbers does not imply that the new (1998) guideline protocols were used.

Table A.5.1 Toxicology Data Requirements for Tebuconazole

Test		Technical	
		Required	Satisfied
870.1100	Acute Oral Toxicity	yes	yes
870.1200	Acute Dermal Toxicity	yes	yes
870.1300	Acute Inhalation Toxicity	yes	yes
870.2400	Primary Eye Irritation	yes	yes
870.2500	Primary Dermal Irritation	yes	yes
870.2600	Dermal Sensitization	yes	yes
870.3100	Oral Subchronic (rodent)	yes	yes
870.3150	Oral Subchronic (nonrodent)	yes	yes
870.3200	21-Day Dermal	yes	yes
870.3250	90-Day Dermal	CR	no
870.3465	90-Day Inhalation	yes	yes+
870.3700a	Developmental Toxicity (rodent)	yes	yes
870.3700b	Developmental Toxicity (nonrodent)	yes	yes
870.3800	Reproduction	yes	yes
870.4100a	Chronic Toxicity (rodent)	no	no
870.4100b	Chronic Toxicity (nonrodent)	yes	yes
870.4200a	Oncogenicity (rat)	no	—
870.4200b	Oncogenicity (mouse)	yes	yes
870.4300	Chronic/Oncogenicity	yes	yes
870.5100	Mutagenicity—Gene Mutation - bacterial	yes	yes
870.5300	Mutagenicity—Gene Mutation - mammalian	yes	yes
870.5xxx	Mutagenicity—Structural Chromosomal Aberrations	yes	yes
870.5xxx	Mutagenicity—Other Genotoxic Effects		
870.6100a	Acute Delayed Neurotox. (hen)	no	—
870.6100b	90-Day Neurotoxicity (hen)	no	—
870.6200a	Acute Neurotox. Screening Battery (rat)	yes	yes
870.6200b	90-Day Neuro. Screening Battery (rat)	yes	yes
870.6300	Develop. Neuro	yes	yes
870.7485	General Metabolism	yes	yes
870.7600	Dermal Penetration	no	yes
870.7800	Immunotoxicity	yes	yes
Special Studies for Ocular Effects			
	Acute Oral (rat)	no	no
	Subchronic Oral (rat)	no	no
	Six-month Oral (dog)	no	no

+: 21-day inhalation toxicity study is available.

Attachment 6

Tolerance/MRL Table

International Residue Limits

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US		Canada	Mexico[1]	Codex[2]
40 CFR §180.474(a) *General.* (1) Compliance with the tolerance levels specified below is to be determined by measuring only tebuconazole [α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol]		α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol		Tebuconazole The residue is fat-soluble.
Commodity	*Tolerance (ppm) /Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[1]	Codex[2]
Almond, hulls	6.0			
Apple, wet pomace	0.1			
Asparagus	0.05			
Banana	0.05	0.03		0.05
Barley, grain	0.3	0.3		2
Barley, hay	7.0			
Barley, straw	3.5			40
Bean, dry seed	0.1			0.3
Bean, succulent	0.1			
Beet, garden, roots	0.70			
Beet, garden, tops	7.0			
Brassica, leafy greens, subgroup 5B	2.5			
Cherry, sweet, pre- and post-harvest	5.0	3 cherry		4 cherries
Cherry, tart, pre- and post-harvest	5.0			
Coffee, green bean[1]	0.15			0.1 coffee beans
Coffee, roasted bean[1]	0.3			
Corn, field, forage	4.0			
Corn, field, grain	0.05	0.05		
Corn, field, stover	3.5			
Corn, pop, grain	0.05			
Corn, pop, stover	3.5			
Corn, sweet, forage	7.0			
Corn, sweet, kernel plus cob with husks removed	0.5	0.5		0.6
Corn, sweet, stover	6.0			
Cotton, gin byproducts	25.0			
Cotton, undelinted seed	2.0			2
Fruit, pome, group 11	0.05			1 apple, pear,
Fruit, stone, group 12, except cherry	1.0	1 nectarines, peaches		2 apricot, nectarine, peach, 1 plums (except prunes) 3 prunes

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US		Canada	Mexico[1]	Codex[2]
Grain, aspirated fractions	16.0			
Grape	5.0	5		6 7 dried grapes (=currants, raisins and sultanas)
Grass, forage	8.0			
Grass, hay	25.0			
Grass, seed screenings	55.0			
Grass, straw	30.0			
Hop, dried cones	35.0			40
Lychee	1.6			
Mango, postharvest	0.15			0.05 mango
Nut, tree, group 14	0.05	0.05		0.05 (*)
Oat, forage	0.10			
Oat, grain	0.15	0.15		2
Oat, hay	0.10			
Oat, straw	0.10			
Onion, bulb, subgroup 3-07A	0.2			0.1 garlic, onion bulb
Onion, green, subgroup 3-07B	1.3			0.7 leek
Orange[1]	1.0			
Orange, oil[1]	10			
Peach	1.0	1		2
Peanut	0.1			0.15 40 peanut fodder
Pistachio	0.05	0.05		0.05 (*) tree nuts
Plum, pre- and post-harvest	1.0			1 (except prunes)
Soybean, forage	25			
Soybean, hay	50			
Soybean, seed	0.08	0.08		0.15
Sunflower, seed	0.05			
Sunflower, meal	0.2			
Sunflower, refined oil	0.2			
Vegetable, cucurbit, group 9	0.4	0.4		0.15 cucumber, melons (except watermelon), 0.2 squash summer 0.1 watermelon (proposed)
Vegetable, fruiting, group 8-10	1.3			0.1 Eggplant 10 peppers, chili, dried 1 peppers sweet (including pimento or pimiento) 0.7 tomato
Wheat, forage	3.0			
Wheat, germ	0.20			
Wheat, grain	0.15	0.15		0.15 wheat, triticale
Wheat, hay	7.0			
Wheat, shorts	0.20			
Wheat, straw	1.5			40
MRLs with NO US Equivalent				
Artichoke				0.6
Broccoli				0.2

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US		Canada	Mexico[1]	Codex[2]
Brussels sprouts				0.3
Cabbages, head				1
Carrot				0.4
Cauliflower				0.05 (*)
Common bean (pods and/or immature seeds) (proposed)				2 (proposed)
Elderberries				1.5
Lettuce, head				5
Olives				0.05 (*)
Papaya				2
Passion fruit				0.1
Rapeseed				0.3
Rice				1.5
Rye				0.15
Rye straw and fodder, dry				40
(2) Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) and its diol metabolite (1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol), calculated as the stoichiometric equivalent of tebuconazole		α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, including the metabolite 5-(4-chlorophenyl)-2,2-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-pentanediol		Tebuconazole The residue is fat-soluble.
Commodity	*Tolerance (ppm) /Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[1]	Codex[2]
Cattle, meat byproducts	0.2	0.2		0.05 (*)
Goat, meat byproducts	0.2	0.2		0.05 (*)
Horse, meat byproducts	0.2	0.2		0.05 (*)
Milk	0.1	0.1		0.01 (*)
Sheep, meat byproducts	0.2	0.2		0.2
MRLs with NO US Equivalent				
Eggs		0.1		0.05 (*)
Meat byproducts of hogs		0.2		0.2
Meat byproducts of poultry		0.1		0.05 (*)
Meat of (cattle, goats, hogs, horses, sheep)		0.2		0.05 (*)
Meat of poultry		0.1		0.05 (*)
M. Negussie; 10/08/15				

[1]There are no U.S. registrations.

[2]Mexico adopts U.S. tolerances and/or Codex MRLs for its export purposes.

[3]* = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat. (fat) = to be measured on the fat portion of the sample. MRLs indicated as proposed have not been finalized by the CCPR and the CAC.

(c) *Tolerances with regional registrations.* Tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the

tolerance levels specified below is to be determined by measuring only tebuconazole, alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on the commodity.

Commodity	Parts per million
Turnip, roots	0.5
Turnip, tops	7.0